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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/599,662 | 10/04/2006 | J. Kern Buckner | 0025.62/PCT-US | 2433 |

25871 7590 05/12/2009

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| EXAMINER | |
|---|---|
| PORTER, JR, GARY A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3766 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 05/12/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efspatents@sbiplaw.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/599,662 | BUCKNER ET AL. | |
| | Examiner | Art Unit | |
| | GARY A. PORTER, JR | 3766 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5,7,13-15,17,20,26,29,34,36,40,43,44,46,59-62,68,69,71,75,78,80 and 89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *44,46 and 59-62* is/are allowed.

6)☒ Claim(s) *1-5,7,13-15,17,20,26,29,34,36,40,43,68,69,71,75,78,80 and 89* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-5, 7, 13-15, 17, 20 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding Claim 1, claim element "assisting means operatively associated with the frame..." is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. Specifically, the Examiner could only find in the disclosure a reference to a spring 240 that "mechanically assists in moving the ventricle toward and end diastole diameter (paragraph [0092])." However, this spring is only found in a "second embodiment" disclosed by Applicant (paragraphs [0038-0045]; Fig. 13-20), which does not include a frame element of the "first embodiment" (paragraph [0026-0037]; Fig. 1-12).

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

4. The Examiner also notes that if Applicant intends the bistable element as recited in Claims 5, 7, 13-15 and 17 to be the "assisting means", the claims are indefinite. Specifically, as claimed in Claim 5, the bistable element is claimed as a separate component from the elements recited in Claim 1. Therefore, when viewing Claims 1 and 5 as a whole, Applicant claims a frame, an assisting means, a limiting means, and a separate bistable element, which precludes the bistable element from being the assisting means. Furthermore, this further precludes any of the structure, as claimed in dependent claims 7, 13-15 and 17, associated with the bistable element from being associated with the "assisting means" of Claim 1. Further clarification on the record of the "assisting means" is required to overcome the rejection.

5. In regards to Claim 1, the claim limitation "assisting means operatively associated with the frame for…" uses the phrase "means for" or "step for", but it is modified by some structure, material, or acts recited in Claim 20. It is unclear whether the recited structure, material, or acts are sufficient for performing the claimed function which would preclude application of 35 U.S.C. 112, sixth paragraph, because the

resilient band and spring element appear capable of performing the desired functionality set forth in the "means for" language of Claim 1.

6. If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to amend the claim so that the phrase “means for” or “step for” is clearly **not** modified by sufficient structure, material, or acts for performing the claimed function.

7. If applicant does **not** wish to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to amend the claim so that it will clearly not be a means (or step) plus function limitation (e.g., deleting the phrase “means for” or “step for”).

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Melvin et al. (US Pub. 2003/0023132).

10. Regarding Clam 29, Melvin discloses disposing a frame within a chamber of the heart, i.e. the ventricle, and storing energy in its springs during systolic ejection (Section [0091]; Fig. 19). This energy is released during diastole to enhance diastolic filling (Section [0092]). Melvin further discloses that restraining bars 111 limit the end diastolic and systolic volumes (Sections [0083, 0092]).

11. Claims 1-4, 20, 26, 29, 34, 43, 44, 59, 60, 68, 69, 71, 75, 78 and 89 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrazzi (US Pub. 2003/0158570).

12. Regarding Claim 1, Ferrazzi teaches an apparatus implantable in a heart ventricle comprising a frame 7 (Fig. 9) configured to engage an inner circumferential periphery of a ventricle and to expand and contract between an expanded diastolic state and a contracted systolic state (Section [0077]); assisting means 10 operatively associated with the frame for mechanically assisting movement of the ventricle toward at least one of an end systolic diameter during systole and an end diastolic diameter during diastole (Sections [0077,0081]); and means 6 and 8 operatively associated with the frame for limiting the ventricle to a predetermined extent (Sections [0077, 0080]; Fig. 9).

13. In regards to Claim 2, Ferrazzi teaches the assisting means 6 and 8 assists movement of the ventricle toward both end systolic diameter during systole and end diastolic diameter during diastole (Section [0077]).

14. With regards to Claim 3, Ferrazzi teaches that during diastole, the assisting means solely assist in limiting ventricular expansion to a predetermined extent (Section [0077]).

15. Regarding Claim 4, Ferrazzi teaches that the assisting means 10 is integrally formed, i.e. attached, to the frame 7 (Section [0080]).

16. In regards to Claim 20, Ferrazzi teaches a resilient band 7; a spring element 8 operatively associated axially with the resilient band 7; and means for joining the ends

of the resilient band into a circle, which is inherent since band 7 is circular; the resilient band being configured, with the ends joined, to engage an inner circumferential periphery of a ventricle, with the spring element in a relaxed state during an end diastolic state of the ventricle, since the band is not under compression in diastole (Section [0051]; Fig. 9).

17. With regards to Claim 26, Ferrazzi teaches a mitral annuloplasty ring 6 extending axially of the resilient band 7 with the resilient band 7 formed into a circle (Fig. 9).

18. Regarding Claim 29, Ferrazzi teaches inserting a device within a ventricle of a patient (Section [0068]). Ferrazzi further teaches that the device mechanically assists movement of the ventricle toward at least one of an end systolic diameter during systole and an end diastolic diameter during diastole (Section [0077]). The device also limits the ventricle to a select end diastolic internal diameter, i.e. allows its radial dilation to a predetermined useful extent (Section [0077]). Lastly, Ferrazzi teaches attaching the device to a portion of myocardium defining an inner circumferential periphery of the ventricle (Section [0079]).

19. In regards to Claim 34, Ferrazzi teaches that in the inserting step, the apparatus comprises a resilient band 7 comprising at least one spring element operatively associated axially with the resilient band 7 (Section [0075]) to allow axial stretching and compression of the resilient band 7, the inserting step further comprising placing the resilient band 7 into contact with the inner circumferential periphery of the ventricle and forming the resilient band 7 into a loop of a diameter about equal to an end diastolic

diameter of an inner circumferential periphery of the ventricle (Section [0077-0079]; Fig. 9).

20. With regards to Claim 43, Ferrazzi teaches that the resilient band further comprises a mitral annuloplasty ring 6 extending axially of the resilient band 7 with the resilient band 7 formed into a circle, the method further comprising attaching the mitral annuloplasty ring 6 to the myocardium below but proximate the mitral annulus (Fig. 9; Section [0001,0071]).

21. In regards to Claim 59, Ferrazzi teaches that the bistable element is configured to self-bias between the expanded and contracted bistable states. Specifically, the device will expand to a predetermined useful extent, i.e. bistable state 1, and then releases its accumulated elastic energy to revert back to the initial diameter, i.e. bistable state 2 (Section [0077]).

22. With regards to Claim 60, Ferrazzi teaches that element 7 is elliptical in an expanded state (Section [0068]); Fig. 9). The Examiner takes Official Notice that since element 7 is elastic, when the extremes of the elliptical element 7 that contact the ventricular wall are compressed in systole, the elliptical shape will deform into a generally hour-glass profile. More specifically, since the elements assist in diastole and systole, and are elastic , they will conform to the natural shape of the ventricular walls during each phase.

23. Regarding Claim 68, Ferrazzi teaches a resilient band 7; a spring element 8 operatively associated axially with the resilient band 7; and means for joining the ends of the resilient band into a circle, which is inherent since band 7 is circular; the resilient

band being configured, with the ends joined, to engage an inner circumferential periphery of a ventricle, with the spring element in a relaxed state during an end diastolic state of the ventricle, since the band is not under compression in diastole (Section [0051]; Fig. 9). Ferrazzi further teaches means 10 associated with resilient band 7 for limiting diastole to a predetermined extent (Sections [0077, 0080, and 0081]; Fig. 9 and 10).

24. In regards to Claim 69, Ferrazzi teaches a biocompatible sheath around the resilient band and spring element (Section [0082]).

25. Regarding Claim 71, Ferrazzi teaches the spring element is integrally formed of the resilient band (Section [0075]).

26. In regards to Claim 75, Ferrazzi teaches a mitral annuloplasty ring 6 extending axially of the resilient band 7 with the resilient band 7 formed into a circle (Fig. 9).

27. With regards to Claim 78, Ferrazzi teaches a method of treating cardiac disease comprising providing a resilient band 7 having at least one spring element operatively associated axially with the resilient band to allow axial stretching and compression of the resilient band (Section [0075, 0077-0079]) and means 10 for limiting axial stretching of the resilient band to a predetermined extent (Sections [0077, 0080, 0081]; Fig. 9 and 10), surgically accessing a ventricle of a heart placing the resilient band into contact with the inner circumferential periphery of the ventricle (an inherent step as seen by the location of the device in Fig. 9); forming the resilient band into a loop of a diameter about equal to an end diastolic diameter of an inner circumferential periphery of the

ventricle; and attaching the resilient band loop to the myocardium defining the inner circumferential periphery of the ventricle (Section [0077-0079]; Fig. 9).

28. Regarding Claim 89, Ferrazzi teaches the resilient band further comprises a mitral annuloplasty ring 6 extending axially of the resilient band with the resilient band 7 formed into a circle (Section [0071]; fig. 9), the method further comprising attaching the mitral annuloplasty ring 6 to the myocardium below but proximate the mitral annulus (Section [0071]; Fig. 9).

### *Claim Rejections - 35 USC § 103*

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

30. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

31. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Melvin et al. (US Pub. 2003/0023132) in view of Feld et al. (US Pub. 2004/0002626).

32. Regarding Claim 34, Melvin discloses all of the claimed invention except for a loop shaped strap for connecting together the spring elements 721 to form a more rigid structural frame. However, Feld describes a framework having longitudinal elements 12" for placement within a heart chamber (Fig. 3b-5b). Lacking any criticality, it would have been an obvious substitution to replace the apical end 730 of Melvin with a connecting ring 14 as described by Feld in Fig. 5b, since both configurations perform the same function of linking the distal portions of each longitudinal element together.

33. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Melvin et al. (US Pub. 2003/0023132) in view of Feld et al. (US Pub. 2004/0002626), further in view of Cloud (US Patent 5,184,482). The Melvin and Feld combination discloses all of the claimed invention except for forming the circular band with a circumferential ligature, wherein the ends of the ligature are tied together to form a ring. However, Cloud teaches forming a loop with a resilient material, i.e. a spring metal material, by attaching free ends of the material together (col. 7, lines 40-59). Although Cloud is merely teaching the formation of ear ornaments, the act of tying or connecting free ends of a resilient material together in order to form a loop is illustrated, therefore illustrating that such a method step of formation is not novel. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Melvin and Feld combination to include tying two ends of a material, i.e. spring

metal, together, as taught and suggested by Cloud, for the purpose of creating a resilient ring formation.

34. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Melvin et al. (US Pub. 2003/0023132) in view of Stevens et al. (US Patent 6,125,852). Melvin discloses all of the claimed invention except for performing a surgical ventricular reduction. However, Stevens teaches that it is known in the art to perform a ventricular reduction on a congestive heart failure patient in order to reshape the enlarged heart to a normal size (Abstract; Fig. 3-5). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method in the Melvin reference to include performing a ventricular reduction, as taught and suggested by Stevens, for the purpose of reshaping an enlarged hart to a normal size.

35. Claim 80 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrazzi (US Pub. 2003/0158570) in view of Cloud (U.S. Patent 5,184,482). Ferrazzi discloses a closed circular band placed within the heart (Fig. 3). Ferrazzi does not disclose a resilient band that includes at least one circumferential ligature operatively associated with the resilient band, the circumferential ligature operatively associated with the resilient band, the circumferential ligature having opposing free ends, the method further comprising forming the resilient band into a loop by tying the opposing free ends of the ligature together. However, Cloud teaches forming a loop with a resilient material, i.e. a spring metal material, by attaching free ends of the material together (col. 7, lines 40-

59). Although Cloud is merely teaching the formation of ear ornaments, the act of tying or connecting free ends of a resilient material together in order to form a loop is illustrated, therefore illustrating that such a method step of formation is not novel. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Ferrazzi reference to include tying two ends of a material, i.e. spring metal, together, as taught and suggested by Cloud, for the purpose of creating a resilient ring formation.

***Allowable Subject Matter***

36. Claims 44, 46, 59, and 60-62 are allowed.

37. Claims 5, 7, 13, 14, 15 and 17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

38. Claims 5, 7, 13, 14, 15 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

39. The following is a statement of reasons for the indication of allowable subject matter:

40. Regarding Claim 5, Applicant recites "a bistable element having a contracted stable state and an expanded stable state corresponding to a desired end systolic diameter and an end diastolic diameter." The Examiner notes that the prior art recites elastic elements that limit expansion of the ventricle. Specifically, in regards to Ferrazzi

(2003/0158570), the closest elements to Applicant's invention is plastic in one direction, i.e. stable, but elastic in the other (paragraph [0077-0078]). However, since this element is elastic, it can expand as a function of force applied to it, which makes them unstable. Upon searching the relevant art to Applicant's invention, the Examiner was unable to find any intraventricular element that is stable in expansion and contraction and expands to a specific diameter and contracts to a specific diameter during diastole and systole respectively.

41. In regards to Claims 44 and 61, Applicant recites, "a bistable element configured to engage an inner circumferential periphery of a ventricle, the bistable element having a contracted stable state and an expanded stable state corresponding to a desired end systolic diameter and an end diastolic diameter… (emphasis added)." The Examiner notes that the prior art recites elastic elements that limit expansion of the ventricle. Specifically, in regards to Ferrazzi (2003/0158570), the closest elements to Applicant's invention is plastic in one direction, i.e. stable, but elastic in the other (paragraph [0077-0078]). However, since this element is elastic, it can expand as a function of force applied to it, which makes them unstable. Upon searching the relevant art to Applicant's invention, the Examiner was unable to find any intraventricular element that is stable in expansion and contraction and expands to a specific diameter and contracts to a specific diameter during diastole and systole respectively. As such, Claims 44, 46. 59 and 60-62 are deemed to be allowable.

### *Response to Arguments*

42. Applicant's arguments, see pages 9-12, filed 2/19/2009, with respect to Claims 1, 2-5, 7, 20, 29, 44, 46, 59, 61 and 62 in view of Feld et al. (U.S. Pub 2004/0002626) have been fully considered and are persuasive. The rejections of Claims 1, 2-5, 7, 20, 29, 44, 46, 59, 61 and 62 has been withdrawn.

43. Applicant's arguments filed 2/19/2009 regarding the rejection of Claim 1 by Ferrazzi et al. (2003/0158570) have been fully considered but they are not persuasive. Specifically, Applicant argues at page 12 of the Remarks "Ferrazzi…clearly teaches an elastic resistance to diastolic expansion of the ventricle and thus cannot constitute "means operatively associated with the frame for limiting the ventricle to a select end diastolic internal diameter." The Examiner respectfully disagrees. The Examiner notes, as pointed out in the rejection of Claim 1 above, that Ferrazzi teaches he means 10 does limit the diastolic expansion to a predetermined extent (Section [0077]).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY A. PORTER, JR whose telephone number is (571)270-5419. The examiner can normally be reached on Monday - Thursday, 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. A. P./
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766